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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket No.: 97N-484S

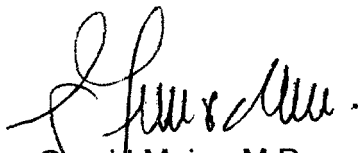
Dear Sirs:

It has been brought to my attention that the FDA is proposing to regulate even more allograft tissue as a medical device.

I- have been using allograft bone from the current bone banks for twenty six (26) years and the FDA already regulates it for safety. I see absolutely no reason for any further regulations. It is already difficult for them to provide the amount of allograft bone that we need, and further 'regulation of these banks is certainly not going to improve their efficiency.

I have never had any difficulties with the present status of the bone banks, and plead with you, please do not add anymore regulations to this group.

Sincerely,



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GM:lmh

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